REMARKS

Applicants respectfully request reconsideration of the present application in view of the reasons that follow.

Applicants thank the Examiner for withdrawing the rejection for lack of description for penetration of the blood-brain barrier and subject matter beyond topical compositions.

STATUS OF CLAIMS

Claim 90, 92-96, 99, 101-105, and 108-111 are under examination.

A detailed listing of all claims that were in the application is presented with an appropriate defined status identifier, regardless of whether the claims remain under examination in the application.

1. Rejection under 35 U.S.C. § 112, first paragraph

The Office rejected claims 90, 92-96, 99, 101-105, and 108-111 for allegedly failing to comply with the enablement and written description requirement.

The Office rejected the claims under § 112 for two limitations, "treating a neurological disorder" and "solvate" (see, e.g., first and last lines of independent claims 90 and 99).

The limitation "treating a neurological disorder"

The Office recognized that the specification satisfies § 112 fully for "stimulating neuronal regeneration and growth" (Office Action, p. 2, ¶ 2). The Office alleges, however, that "treating 'neurological disorder' must treat the disease while neuronal regeneration ... does not necessarily treat what is causing the disease or disorder" (*ibid.*). The Office suggests limiting the claims to "stimulating neuronal regeneration and growth in a mammal" (*ibid.*).

Applicants respectfully decline this invitation to amend the claims and traverse this ground of rejection. Applicants submit that the specification provides full written description support and enablement for the claimed "method of treating a neurological disorder."

The rejection appears primarily based on inoperability under § 101, i.e., insufficient showing that the claimed method could treat a "neurological disorder". As such, the rejection is improper, because the specification presents test data on an animal model for a neurological disorder. The Manual of Patent Examining Procedure (M.P.E.P.) states, "[D]ata generated using in vitro assays, or from testing in an animal model or a combination thereof almost invariably will be sufficient to establish therapeutic or pharmacological utility for a compound, composition or process." M.P.E.P. § 2107.03.III.

Table III contains data based on an animal model of Parkinson's disease (p. 37, ll. 34-35, p. 38, ll. 25-32, and Table III, p. 39, top). Parkinson's disease is a neurological disorder (specification, p. 22, ll. 9-20). Accordingly, the specification presents test data on an animal model for a neurological disorder. To the extent this ground of rejection is based on inoperability under § 101, the rejection is improper. The Manual of Patent Examining Procedure (M.P.E.P.) states, "[D]ata generated using in vitro assays, or from testing in an animal model or a combination thereof almost invariably will be sufficient to establish therapeutic or pharmacological utility for a compound, composition or process." M.P.E.P. § 2107.03.III.

Moreover, the following passages in the specification provide further evidence that the applicants fully contemplated and were in possession of the subject matter of "treating neurological disorders":

> This invention relates to small molecule compounds and compositions, their preparation and use for treating neurological disorders . . . .

P. 1, ll. 16-17.

> The present invention relates to the surprising discovery that N-heterocyclic sulfonamide compounds containing a carboxylic acid or carboxylic acid isostere moiety may be useful for treating neurodegenerative disorders . . . .

P. 4, ll. 18-22, 26-28.

> These compounds stimulate neuronal regeneration and outgrowth and as such are useful for treating neurological disorders and neurodegenerative diseases.

P. 4, ll. 26-28.

> Another preferred embodiment of the invention is a method of promoting neuronal regeneration and growth in mammals, comprising administering to a mammal an effective amount of a N-linked sulfonamide of an N-heterocyclic carboxylic acid or carboxylic acid isostere.

P. 9, ll. 25-31.

> The neurological disorders that may be treated include but are not limited to: trigeminal neuralgia, glossopharyngeal neuralgia, Bell's Palsy, myasthenia gravis, muscular dystrophy, amyotrophic lateral sclerosis, progressive muscular atrophy, progressive bulbar inherited muscular atrophy, herniated, ruptured or prolapsed invertebrate disk syndromes, cervical spondylosis, plexus disorders, thoracic outlet destruction syndromes, peripheral neuropathic such as those caused by lead, dapsone, ticks, prophyria, or Gullain-Barre syndrome, Alzheimer's disease, and Parkinson's disease.

P. 22, ll. 8-20.

> The present invention also relates to the use of carboxylic acid and carboxylic acid isostere compounds for treating the above-mentioned neuropathies, neurological disorders, and neurological damage.

P. 37, ll. 3-7.

The specification defines "treatment" at p. 18, l. 29, to p. 19, l. 5.

Finally, Examples 20-28 disclose treating neurological disorders (p. 52, l. 8, to p. 54, l. 4).

The limitation "solvates"

Applicants respectfully submit that the term "solvates" is well-known to persons of skill in the art, is commonly used in patent claims under standard U.S. practice, and should

not be the basis of a rejection under 35 U.S.C. § 112. The USPTO has issued 2,905 patents containing the term "solvate" in the claims. The examiner of the present application has allowed at least 20 patents containing the same term in the claims.

Applicants attach herewith the results of two electronic searches conducted in the USPTO Patent Full-Text and Image Database in support of these assertions. The claims of the retrieved patents use the term "solvate" in essentially the same manner as the claim of the present application. For example, "A pharmaceutical composition comprising: "a compound of formula I ... or a pharmaceutically acceptable salt, ester, or solvate of the compound" (claim 1 of U.S. 7,153,883); "A compound of formula (I) ... or a pharmaceutically acceptable salt or solvate thereof" (claim 1 of U.S. 7,078,424); "A compound of the formula I: ... or a pharmaceutically acceptable salt or solvate of said compound" (claim 1 of U.S. 7,071,213).

In light of the foregoing, Applicants respectfully request reconsideration and withdrawal of the rejections under § 112, first paragraph.

CONCLUSION

Applicants believe that the present amendment places the application in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the application to allowance.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check or credit card payment form being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741.

If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

Date 24-Jan-2007 By _____

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